



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1575]

Best Practices for Communication Between the Food and Drug Administration and
Investigational New Drug Sponsors During Drug Development; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive suggestions, recommendations, and comments from interested parties, including academic institutions, regulated industry, and other interested organizations on best practices for communication between FDA and investigational new drug application (IND) sponsors during drug development. These comments will help FDA identify and ultimately establish best practices to be included in a draft guidance for industry and review staff.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel E. Hartford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6312, Silver Spring, MD 20993-0002, 301-796-0331, email: ONDEnhancedComm@fda.hhs.gov; or

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration,
10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

One of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA) under Title I of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), related to promoting innovation through enhanced communication between FDA and sponsors during drug (including biological product) development, is for FDA to publish draft guidance for industry and review staff describing best practices for communication between FDA and IND sponsors during drug development. (A copy of the PDUFA Reauthorization Performance Goals and Procedures; Fiscal Years 2013 Through 2017 is available on the FDA Web site at <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.)

The guidance will describe FDA's philosophy regarding timely interactive communication with IND sponsors as a core activity and the scope of appropriate interactions between the review team and the sponsor, outline the types of advice that are appropriate for sponsors to seek from FDA in pursuing their drug development program, describe the general expectations for the timing of FDA response to IND sponsor inquiries of simple and clarifying questions or referral of more complex questions to the formal meeting process, and describe best practices and communication methods (including the value of person-to-person scientific dialogue) to facilitate interactions between the FDA review team and the IND sponsor during drug development. We anticipate that the best practices will include expectations and agreement

on appropriate methods (e.g., when teleconferencing or secure email may be the most appropriate means of communication) and frequency of such communications.

II. Establishment of a Docket and Request for Comments

To help FDA identify and ultimately establish best practices to be included in a draft guidance, FDA is requesting public suggestions, recommendations, and comments for each aspect of the best practices mentioned above. FDA will consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: October 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.